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Genzyme Corporation,
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GENZYME CORPORATION, SOUTHERN RESEARCH INSTITUTE, and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. EMCURE PHARMACEUTICALS USA, INC. and EMCURE PHARMACEUTICALS LTD, Defendants.	Civil Action No. **COMPLAINT** *Electronically Filed*

Plaintiffs Genzyme Corporation ("Genzyme"), Southern Research Institute ("Southern Research"), and sanofi-aventis U.S. LLC ("Sanofi") (collectively, "Plaintiffs") by their attorneys,

for their Complaint against Emcure Pharmaceuticals USA, Inc. and Emcure Pharmaceuticals Ltd. (collectively, "Emcure") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Emcure Pharmaceuticals Ltd. ("Emcure Ltd.") with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Genzyme's Clolar® drug product.

THE PARTIES

2. Genzyme is a corporation organized and existing under the laws of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142. Genzyme sells drug products containing clofarabine in the United States under the trademark Clolar®.

3. Southern Research is a corporation organized and existing under the laws of Alabama, having its principal place of business at 2000 Ninth Avenue South, P.O. Box 55305, Birmingham, Alabama 35205-5305.

4. Sanofi is a Delaware corporation with its principal place of business in Bridgewater, New Jersey.

5. On information and belief, Defendant Emcure Ltd. is a corporation organized and existing under the laws of India having a place of business at Emcure House, T 184, M.I.D.C., Bhosari, Pune, 411 026, India.

6. On information and belief, Defendant Emcure Pharmaceuticals USA, Inc. ("Emcure Inc.") is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 21/B Cotters Lane, East Brunswick, New Jersey 08816.

7. On information and belief, Emcure Inc. is a wholly owned subsidiary of Emcure Ltd. and is controlled and/or dominated by Emcure Ltd.

8. On information and belief, Emcure Ltd. operates in the United States through Emcure Inc.

9. On information and belief, Emcure Inc. and Emcure Ltd. have common officers and directors, and Emcure Ltd. and Emcure Inc. have represented to the public that they are a unitary entity.

10. On information and belief, the acts of Emcure Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Emcure Ltd. On information and belief, the acts of Emcure Inc. complained of herein were done at least in part for the benefit of Emcure Ltd.

11. On information and belief, the acts of Emcure Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Emcure Inc. On information and belief, the acts of Emcure Ltd. complained of herein were done at least in part for the benefit of Emcure Inc.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. On information and belief, Emcure Inc. and Emcure Ltd. are in the business of developing, formulating, manufacturing, offering to sell, selling, commercializing, and

marketing generic versions of branded pharmaceutical products for distribution in the United States, including in the State of New Jersey.

14. On information and belief, Emcure Inc. and Emcure Ltd. operate as an integrated, unitary business.

15. On information and belief, Emcure Inc. and Emcure Ltd. directly, or indirectly through subsidiaries and/or distributors, develop, manufacture, market, distribute, and sell pharmaceutical products within and throughout the United States, including in the State of New Jersey.

16. On information and belief, Emcure Inc. and Emcure Ltd. have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including in the State of New Jersey, and/or by selling, directly or through their agents, pharmaceutical products in the State of New Jersey.

17. On information and belief, Emcure Inc. and Emcure Ltd. have generated significant revenue from purchases made by Emcure's pharmaceutical product customers, who are located throughout the United States, including within the State of New Jersey.

18. On information and belief, Emcure Inc. and Emcure Ltd. acted in concert to develop Emcure Ltd.'s generic copy of Genzyme's Clolar® drug product, and to seek approval from the FDA to sell Emcure Ltd.'s generic copy of Genzyme's Clolar® drug product throughout the United States and within the State of New Jersey.

19. On information and belief and as stated in the letter dated August 8, 2014, purporting to be a notice pursuant to 21 C.F.R. § 314.95 (the "Notice Letter"), Emcure Ltd. submitted ANDA No. 206972 to the FDA.

20. On information and belief and as stated in the Notice Letter, Emcure Ltd. notified Plaintiffs that Emcure Ltd. had submitted ANDA No. 206972, seeking approval to market Emcure Ltd.'s generic copy of Genzyme's Clolar® drug product, and that Emcure Ltd. was providing information to Plaintiffs pursuant to § 505(j)(2)(B)(ii) of the Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and § 314.95 of Title 21 of the Code of Federal Regulations.

21. On information and belief, Emcure Inc. and Emcure Ltd. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., Novartis Pharmaceuticals Corp. v. Actavis et al.*, 2:12-cv-3967-SDW-MCA (D.N.J.); *Astellas US LLC et al. v. Emcure Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:14-cv-01665-SRC-CLW (D.N.J.); *Cephalon, Inc. v. Emcure Pharmaceuticals Ltd. et al.*, Civil Action No. 3:14-cv-01705-PGS-DEA (D.N.J.); *Fresenius Kabi USA, LLC v. Emcure Pharmaceuticals USA, Inc. el al.*, Civil Action No. 1:14-cv-05584-JEI-JS (D.N.J.).

22. On information and belief, Emcure Ltd. has continuous and systematic contacts with New Jersey, including, but not limited to, ongoing communications and contacts with Emcure Inc.

23. On information and belief, Emcure Ltd. has availed itself of the laws of the State of New Jersey and engaged in a course of conduct in the State of New Jersey, at least by incorporating its U.S. subsidiary, Emcure Inc., under New Jersey law.

24. On information and belief, by virtue of, *inter alia*, the sales-related activities of Emcure Ltd. in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey; Emcure Ltd.'s relationship with Emcure Inc., including in connection with the preparation and/or filing of ANDA No. 206972; and Emcure Ltd.'s continuous and systematic

contacts with New Jersey, this Court has personal jurisdiction over Emcure Ltd. These activities satisfy due process and confer personal jurisdiction over Emcure consistent with New Jersey law.

25. This Court has personal jurisdiction over Emcure Inc. by virtue of its presence and incorporation in New Jersey.

26. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT

27. United States Patent No. 5,661,136 ("'136 patent") was duly and legally issued on August 26, 1997 to inventors Drs. John A. Montgomery and John A. Secrist, III. The '136 patent was assigned to Southern Research. With patent term extension, the '136 patent will expire on January 14, 2018. At all times from the issuance of the '136 patent to the present, Southern Research has been the owner of the '136 patent. Genzyme is Southern Research's exclusive licensee under the '136 patent. Sanofi is Genzyme's exclusive sub-licensee under the '136 patent.

ACTS GIVING RISE TO THIS ACTION

28. By the Notice Letter dated August 8, 2014, purporting to be a notice pursuant to Section 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) and 21 C.F.R. § 314.95, Emcure Ltd. notified Plaintiffs that Emcure Ltd. had submitted ANDA No. 206972 to the FDA under Section 505(j) seeking approval to engage in the commercial manufacture, importation, use, and sale of 20mg/20ml clofarabine injection ("Clofarabine ANDA Injection") as a generic version of Genzyme's Clolar® drug product. Southern Research, Genzyme, and Sanofi all share in the revenue generated from the sale of Genzyme's Clolar® drug product.

29. On information and belief, Emcure Ltd. asserted in its ANDA that its Clofarabine ANDA Injection is bioequivalent to Genzyme's 20 mL clofarabine Clolar® drug product.

30. Emcure Ltd.'s ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, offer to sell, and sale of Emcure Ltd.'s Clofarabine ANDA Injection prior to the expiration of the '136 patent, which is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Genzyme's Clolar® drug product.

31. On information and belief, Emcure intends to engage in the commercial manufacture, importation, use, offer to sell, and sale of Emcure Ltd.'s Clofarabine ANDA Injection promptly upon receiving FDA approval to do so.

32. In the Notice Letter, Emcure Ltd. notified plaintiffs that its ANDA contained a "Paragraph IV" certification that in Emcure Ltd.'s opinion the '136 patent is invalid or will not be infringed by the commercial manufacture, use, sale, offer to sell, or importation of Emcure Ltd.'s Clofarabine ANDA Injection.

COUNT I
INFRINGEMENT BY EMCURE LTD. OF U.S. PATENT NO. 5,661,136

33. Plaintiffs repeat and reallege the allegations of paragraphs 1-32 as if fully set forth herein.

34. Emcure Ltd.'s submission of its ANDA to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer to sell, or sale of its Clofarabine ANDA Injection prior to the expiration of the '136 patent constitutes infringement of one or more of the claims of the '136 patent, including but not limited to Claim 1, under 35 U.S.C. § 271(e)(2)(A).

35. Emcure Ltd. had notice of the '136 patent at the time of its infringement. Emcure Ltd.'s infringement has been, and continues to be, deliberate.

36. Plaintiffs will be substantially and irreparably harmed if Emcure Ltd.'s infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT BY EMCURE OF U.S. PATENT NO. 5,661,136

37. Plaintiffs repeat and reallege the allegations of paragraphs 1-36 as if fully set forth herein.

38. This claim arises under the Patent Laws, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties. Emcure has taken immediate and active steps, through Emcure's submission of its ANDA, to obtain approval from the FDA and, after obtaining FDA approval, to engage in the commercial manufacture, importation, use, offer to sell, or sale of its Clofarabine ANDA Injection in the United States prior to the expiration date of the '136 patent. There is a real and actual controversy between the parties with respect to Emcure's intent to engage in the commercial manufacture, importation, use, offer to sell, or sale of its Clofarabine ANDA Injection upon receiving FDA approval and infringement of the '136 patent.

39. Emcure's commercial manufacture, importation, use, offer to sell, or sale of its Clofarabine ANDA Injection in/into the United States, prior to the expiration of the '136 patent, would constitute infringement of one or more of the claims of the '136 patent, including but not limited to Claim 1, under 35 U.S.C. §§ 271(a), (b) and/or (c).

40. Upon FDA approval of Emcure's ANDA, Emcure will infringe one or more of the claims of the '136 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or

importing its Clofarabine ANDA Injection in/into the United States, unless enjoined by this Court.

41. Upon FDA approval of Emcure's ANDA, Emcure will infringe one or more of the claims of the '136 patent under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

42. Emcure had notice of the '136 patent at the time of its infringement. Emcure's infringement has been, and will continue to be, deliberate.

43. Plaintiffs will be substantially and irreparably harmed if Emcure's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully request the following relief:

(a) A judgment declaring that Emcure has infringed one or more claims of the '136 patent by the filing of ANDA No. 206972;

(b) A judgment declaring that Emcure's commercial making, using, selling, offering to sell, or importing its Clofarabine ANDA Injection in/into the United States will infringe one or more claims of the '136 patent;

(c) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 206972 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date no earlier than January 14, 2018, the date on which the '136 patent expires, or the expiration of any other exclusivity to which Genzyme or Southern Research becomes entitled;

(d) Injunctive relief under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Emcure from making, using, selling, offering to sell, or importing its Clofarabine ANDA

Injection in/into the United States until after expiration of the '136 patent or the expiration of any other exclusivity to which Genzyme or Southern Research becomes entitled;

(e) Damages under 35 U.S.C. § 271(e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if Emcure infringes the '136 patent by engaging in the commercial manufacture, importation, use, sale, offer to sell or import its Clofarabine ANDA Injection in/into the United States prior to the expiration of the '136 patent or the expiration of any other exclusivity to which Genzyme or Southern Research becomes entitled;

(f) An award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(g) Costs and expenses in this action; and

(h) Such further and other relief as this Court may deem just and proper.

DATED: September 24, 2014

CONNELL FOLEY LLP

s/Liza M. Walsh

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RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is related to the following action pending before the Honorable Joseph E. Irenas, U.S.D.J. and the Honorable Karen M. Williams, U.S.M.J., in the United States District Court, District of New Jersey: *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 13-6827.

I certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding other than the above referenced matter, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

DATED: September 24, 2014

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RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, injunctive relief.

DATED: September 24, 2014

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